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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/943,550	08/30/2001	William Vanbrooks Harrison	AB-146U	9637

23845 7590 10/23/2003

ADVANCED BIONICS CORPORATION
12740 SAN FERNANDO ROAD
SYLMAR, CA 91342

EXAMINER

OROPEZA, FRANCES P

ART UNIT	PAPER NUMBER
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3762

DATE MAILED: 10/23/2003

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Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/943,550

Applicant(s)

HARRISON ET AL.

Examiner

Frances P. Oropeza

Art Unit

3762

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 8/30/01 (Initial Filing).
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-26 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-26 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 30 August 2001 is/are: a) ☐ accepted or b) ☒ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 2,3.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). _____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____.

DETAILED ACTION

Claim Rejections - 35 USC § 102

1. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

Claims 1, 2, 6-15, 17, 19-22 and 26 are rejected under 35 U.S.C. 102(e) as being anticipated by Ishikawa et al. (US 6464687). Ishikawa et al. disclose an implantable system that modulates blood flow/ circulatory profusion (col. 13 @ 27-30) using a unit(s) that is near a vessel (col. 11 @ 5-10) to measure the flow, deliver the drugs in response to the flow (col. 5 @ 34-39; col. 6 @ 25-32; col. 11 @ 5-7), and/or provide electrical stimulation in response to the flow (col. 3 @ 53-56; col. 6 @ 25-32; col. 13 @ 24-27; col. 29 @ 33-36) by impacting the vessel/ smooth muscle/ skeletal muscle (tissue) /vascular tissue/ neural tissue (col. 2 @ 54-56 and 66-67; col. 4 @ 45-50; col. 9 @ 1-12; col. 11 @ 53-54). Control can be aggregated or the devices can operate independently, and the control can be internal or external (Abstract; col. 4 @ 35-39). The treatment site can be local or remote to the monitoring site (col. 7 @ 7-10). Flow in the vessel is monitored, and the drugs and electrical stimulation are controlled to create hypofusion or hyperfusion.

Claim Rejections - 35 USC § 103

2. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint Inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the Examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. The Applicant is advised of the obligation under 37 CFR 1.56 to point out the Inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

3. Claims 3 and 4 are rejected under 35 U.S.C. 103(a) as being unpatentable over Ishikawa et al. (US 6464687) in view of Garfield et al. (US 6356777). As discussed in paragraph 1 of this action, Ishikawa et al. discloses the claimed invention except for stimulating the muscle at greater than 50 Hz to relax the muscle (claim 3), and stimulating the muscle at less than 50 Hertz to excite the muscle.

Garfield et al. teach muscle control using frequencies above and below 50 Hz to create a stimulated and relaxed muscle respectively for the purpose of altering the state of contraction. It would have been obvious to one having ordinary skill in the art at the time of the invention to have used stimulation of the muscle above and below 50 Hz in the Ishikawa et al. system in order to provide a stimulation level known to create stimulation and relaxation of muscle tissue so levels of stimulation of the tissue/ muscles can be evaluated and optimal treatment levels adopted (Abstract; col. 3 @ 55-63; col. 11 @ 17-23).

4. Claims 5 and 25 are rejected under 35 U.S.C. 103(a) as being unpatentable over Ishikawa et al. (US 6464687) in view of Hobbs et al. (US 5916154). As discussed in paragraph 1 of this action, Ishikawa et al. disclose the claimed invention except for the stimulation level being less than about 1-10 mA.

Hobbs teaches tissue control using stimulation ranges of 1-5 mA for the purpose of relaxing the muscle, hence increasing flow in the vessel. It would have been obvious to one having ordinary skill in the art at the time of the invention to have used stimulation in the 1-5 mA range in the Ishikawa et al. system in order to provide a stimulation level known to create relaxation of the tissue so the flow level in vessel can be altered to an advantageous level for the patient to maintain an optimum pulse amplitude (Abstract; col. 2 @ 40-46).

5. Claims 16 and 18 are rejected under 35 U.S.C. 103(a) as being unpatentable over Ishikawa et al. (US 6464687) in view of Keogh et al. (US 6447443). As discussed in paragraph 1 of this action, Ishikawa et al. disclose the claimed invention except for the drugs to alter perfusion being sympathetic antagonist and inhibitory neurotransmitter antagonist.

Keogh et al. teaches altering heart rhythms and perfusion using sympathetic antagonist and inhibitory neurotransmitter antagonist for the purpose of controlling blood flow and vessel dilation. It would have been obvious to one having ordinary skill in the art at the time of the invention to have used a sympathetic antagonist and inhibitory neurotransmitter antagonist in the Ishikawa et al. system in order to provide drugs known to impact perfusion so the patient's condition can be effectively optimized (col. 23 @ 51-53; col. 24 @ 6-12 and 60-64; col. 25 @ 62-67; col. 27 @ 24-26 and 42-56; col. 29 @ 47-50).

6. Claims 23 and 24 are rejected under 35 U.S.C. 103(a) as being unpatentable over Ishikawa et al. (US 6464687) in view of Kieval et al. (US 6073048). As discussed in paragraph 1 of this action, Ishikawa et al. discloses the claimed invention except for electrical stimulation exciting the parasympathetic neural activity (claim 23), or inhibiting the sympathetic neural activity (claim 24).

Kieval et al. teaches neural stimulation using stimulation of the sympathetic/ parasympathetic systems for the purpose of inhibiting/ exciting neural activity. It would have been obvious to one having ordinary skill in the art at the time of the invention to have used sympathetic and parasympathetic stimulation in the Ishikawa et al. system in order to provide control that enable the vascular tone to be adjusted so perfusion of the vascular system is optimized (col. 1 @ 39-49; col. 1 @ 60 – col. 2 @ 3).

Drawings

7. Figures 5 and 6 are objected to under 37 CFR 1.83(a) because the rectangular boxes are not labeled as described in the specification (figure 6) or are label with acronyms that are not commonly understood (figure 5). Any structural detail that is essential for a proper understanding of the disclosed invention should be shown in the drawing. MPEP § 608.02(d). A proposed drawing correction or corrected drawings are required in reply to the Office action to avoid abandonment of the application. The objection to the drawings will not be held in abeyance.

Specification

8. The disclosure is objected to because on page 25, line 25, it appears “Fig. 9” should be --Fig. 7--. Appropriate correction is required.

Information Disclosure Statement

9. References appearing to relate to this application were found in the case, but there was no associated PTO-1449. The Examiner has reviewed two IDSs and signed two PTO-1449s, but if the Applicant submitted a third IDS the only part missing may be the associated PTO-1449.

Conclusion

Any inquiry concerning this communication or earlier communications from the Examiner should be directed to Fran Oropeza, telephone number is (703) 605-4355. The Examiner can normally be reached on Monday – Thursday from 6 a.m. to 4:30 p.m.

If attempts to reach the Examiner by telephone are unsuccessful, the Examiner's Supervisor, Angela D. Sykes can be reached on (703) 308-5181. The fax phone number for the organization where this application or proceeding is assigned is (703) 306-4520 for regular communication and for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Receptionist, telephone number is (703) 308-0858.

Frances P. Oropeza
Patent Examiner
Art Unit 3762

FPO
10/17/03

Angela D. Sykes

ANGELA D. SYKES
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 3700